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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,272	02/14/2002	Robert K. Yang	1199-4	4926
7590	07/02/2004		EXAMINER	
Daniel A. Scola, Jr. HOFFMANN & BARON, LLP 6900 Jericho Turnpike Syosset, NY 11791			LAZOR, MICHELLE A	
			ART UNIT	PAPER NUMBER
			1734	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/074,272	YANG ET AL.
	Examiner	Art Unit
	Michelle A Lazor	1734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-22,32-50 and 56-61 is/are withdrawn from consideration.
- 5) Claim(s) 54 and 55 is/are allowed.
- 6) Claim(s) 23-31 and 51-53 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/03,3/02 &amp; 3/02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 – 22, 37 – 43, 47 – 50, 56 – 61, drawn to a product, classified in class 424, subclass 488.
  - II. Claims 23 – 31 and 51 – 55, drawn to a process, classified in class 264, subclass 175.
  - III. Claims 32 – 36 and 44 – 46, drawn to a method, classified in class 424, subclass 434.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as drying said film in a controlled manner from the top, or making a film not used for enteral or topical administration.
3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different

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process of using that product, such as introducing the film to the oral cavity of a fish or using the film other than for administration of an active component in a dosage form or placing said film into a liquid where it does not dissolve.

4. Inventions II and III are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Anna-Lisa Gallo on 5/18/04 a provisional election was made with traverse to prosecute invention II, claims 23 – 31 and 51 – 55. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1 – 22, 32 – 50, and 56 – 61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 23 – 26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Zerbe et al. (U.S. Patent No. 6284264).

Zerbe et al. disclose a process comprising combining a polymer component, a polar solvent, and an active component to form a matrix with a uniform distribution of said components; forming an ingestible film from said matrix; providing a surface having top and bottom sides; feeding said film onto said top side of said surface; and drying said film by applying heat to what is considered said bottom side of said surface by using a drying tunnel or oven, which would heat all around said film including said bottom side of said surface; wherein said drying step maintains a non-self-aggregating uniform heterogeneity of said components throughout said film; and wherein said film is considered to be self-supporting (column 3, line 48 – column 4, line 15). Thus Zerbe et al. disclose all the limitations of Claims 23 – 26 and 28, and anticipate the claimed invention.

9. Claims 23 – 28 and 51 – 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Lin et al. (EP 1110546).

Regarding Claims 23 – 28, Lin et al. disclose a process comprising combining a polymer component, a polar solvent, and an active component to form a matrix with a uniform

distribution of said components; forming an ingestible film from said matrix (page 4, paragraph 23); providing a surface having top and bottom sides (page 4, paragraph 22); feeding said film onto said top side of said surface; and drying said film by applying heat to what is considered said bottom side of said surface by using a drying tunnel or oven (page 4, paragraph 29), which would heat all around said film including said bottom side of said surface; wherein said drying step maintains a non-self-aggregating uniform heterogeneity of said components throughout said film; and wherein said film is flexible when dried and self-supporting (Abstract). Thus Lin et al. disclose all the limitations of Claims 23 – 28, and anticipate the claimed invention.

Regarding Claims 51 – 53, Lin et al. disclose polymers selected to provide a viscosity sufficient to maintain said uniform distribution (pages 2 – 3, paragraphs 10, 11, and 18), and disclose forming a film from said matrix by reverse roll coating (page 8, “Casting Device). Thus Lin et al. disclose all the limitations of Claims 51 – 53, and anticipate the claimed invention.

10. Claims 23 – 31 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US Patent No. 6552024).

Chen et al. disclose a process comprising combining a polymer component with a viscosity sufficient to maintain a uniform distribution, a polar solvent, and an active component to form a matrix with said uniform distribution of said components; forming an ingestible film from said matrix; providing a surface having top and bottom sides; feeding said film onto said top side of said surface (Abstract; column 10, line 66 – column 11, line 29); and drying said film by applying heat to what is considered said bottom side of said surface by using a drying tunnel or oven for less than 10 minutes (column 12, lines 1 – 28), which would heat all around said film including said bottom side of said surface; wherein said drying step maintains a non-self-

aggregating uniform heterogeneity of said components throughout said film; wherein said film is flexible when dried and self-supporting (Abstract); and finally, wherein uniform distribution determines the amount of active material component per area and wherein a specific amount of the active material component may be obtained from said film by cutting said film to a predetermined size (column 11, lines 20 – 28). Thus Chen et al. disclose all the limitations of Claims 23 – 31 and 51, and anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. in view of Dohner et al. (U.S. Patent No. 6238700).

Chen et al. disclose a process comprising combining a polymer component, and polar solvent to form a matrix with a uniform distribution of said components, said polymer selected to provide a viscosity sufficient to maintain said uniform distribution; forming a film from said matrix; providing a surface having top and bottom sides; feeding said film onto said top side of said surface (Abstract; column 10, line 66 – column 11, line 29); and drying said film by applying heat to said bottom side of said surface (column 12, lines 1 – 28), as described above, but do not specifically disclose reverse roll coating. However, Dohner et al. disclose various procedures for forming films, including reverse roll coating (column 5, lines 19 – 32). Therefore

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it would have been obvious to one of ordinary skill in the art at the time of the invention to use reverse roll coating as an equivalent alternative to casting a film.

*Allowable Subject Matter*

13. Claims 54 and 55 are allowed. There was no reference in the prior art search that disclosed, taught, or suggested drying said film by feeding said film onto a surface having top and bottom sides, said bottom side being in substantially uniform contact with a water bath at a temperature sufficient to dry said film. The majority of the prior art references found referred to drying of the film using heating ovens or tunnels.

*Conclusion*

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kuroya et al. (U.S. Patent No. 5137729) disclose a soft adhesive film used to deliver drugs (Abstract; column 5, lines 3 – 29).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle A Lazor whose telephone number is 571-272-1232. The examiner can normally be reached on Mon - Wed 6:30 - 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MAL  
6/23/04

  
MICHAEL P. COLAIANNI  
SUPERVISORY PATENT EXAMINER